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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/181,582    10/28/98    JACKSON

J    110129.416

000500    HM22/0220  
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EXAMINER

WEBMAN, F

ART UNIT

PAPER NUMBER

1617  
DATE MAILED:

02/20/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/181582

Applicant(s)

JACKSON

Examiner

WEBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 11/30/00
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-62 is/are pending in the application.
- Of the above claim(s) 2, 24-47, 52-62 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1, 3-23, 48-51 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) 4, 58, 13, 14 ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other \_\_\_\_\_

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Applicant's election with traverse of Group I, the specified "TB" polymer and MePEG in Paper Nos. 11 and 15 is acknowledged. The traversal is on the ground(s) that the process is limited to the claimed polymer. This is not found persuasive because the patentability of process steps is independent of particular ingredients. As to the election of species requirement, neither distinctness nor burden need be shown. Applicants can overcome this requirement by stating on the record that the species are equivalent.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 3-10, 13, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al in view of Hunter et al.

Zhang et al teach a paste composition comprising either a triblock polymer of polyethylene glycol and polylactide, and paclitaxel (abstract).

Hunter et al teach dissolving paclitaxel in methoxypolyethylene glycol (MePEG) 350 prior mixing with a polymer to make a 30:70 MePEG:polymer composition containing 0.2-10% paclitaxel.(col. 60 lines 13-16, 40-41, col. 61 lines 12-13).

It would have been obvious to one of ordinary skill in the art to add MePEG to the composition of Zhang et al to achieve the beneficial effect of dissolving paclitaxel prior to addition to the polymer in view of Hunter et al.

Claims 1, 3-23, 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al '717 in view of Hunter et al.

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Cha et al '717 teach liquid compositions comprising block copolymers of polyhydroxyacids and polyethylene glycol and a drug (abstract). Triblock polymers are specified (col. 7 lines 33-34). Poly(caprolactone co-lactic acid) is disclosed (col. 7 line 44). ABA polymers containing 50-85% B block of polyethylene glycol of molecular weight 1000-5000 and 15-50% A blocks of molecular weight 500-3000 are specified (col. 7 lines 52-55, 61-65, col. 8 lines 29-34). Taxol is specified (claim 32).

Hunter et al is discussed above.

It would have been obvious to one of ordinary skill in the art to add MePEG to the composition of Cha et al '717 to achieve the beneficial effect of dissolving taxol prior to addition of the taxol to the liquid composition in view of Hunter et al. As to the claimed plural drugs, the examiner takes notice under MPEP 2144.03 that it is well-known in the art to deliver plural drugs in one delivery vehicle. As to the claimed molecular weight MePEG and percent paclitaxel, Hunter et al teaches amounts reading on the claimed ranges. As to the claimed paste property of the triblock polymer itself, Cha et al teach polymers of the same composition as the third entry in applicants' Table II.

Claims 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the 200-70/30 PDDL A-PEG-PDDL A and (200-1000)-35/35/30 PLC-PEG-PLC polymers, does not reasonably provide enablement for any triblock polymer of PEG and any mixture of glycolic acid, lactic acid and caprolactone. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make the invention commensurate in scope with these claims. Applicants disclose the property of liquid for only the above cited polymers in Tables I and II.

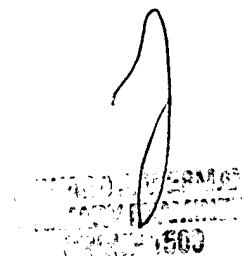
Claims 16-18, 48-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 16-18, 48 the Markush group of alkylene oxide and alkylene glycol is indefinite. Are not polyalkylene oxides, of which polyethylene glycol is a subset (see claim 10), synthesized by the addition reaction of alkylene oxides, which are cyclic ethers (e.g. ethylene oxide or oxirane), rather than the condensation reaction of alkylene glycols? That is, alkylene glycol cannot be a monomer for the claimed B block.

Reference AP (Deng et al) and BH (Youxin et al) were lined through on PTO Form 1449 because only the first page of the former was supplied and because pages 122, 123 are missing from the latter. The examiner requests the Martini et al, Zhang et al, and Ramaswamy et al references cited on page 10 lines 4-7.

No claims allowed.

Any inquiry concerning this communication should be directed to E. Webman at telephone number (703) 308-4432.

A handwritten signature, possibly "E. Webman", is written over a rectangular stamp. The stamp contains the text "RECEIVED" at the top, "FEB 16 2010" in the middle, and "703-308-1500" at the bottom.